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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,953

04/27/2005

Hajime Nakano

10921.314USWO

2021

52835

7590

02/20/2009

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EXAMINER

FRITCHMAN, REBECCA M

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,953	Applicant(s) NAKANO ET AL.0	
	Examiner REBECCA FRITCHMAN	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/08/2006 & 04/27/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the initial Office action based on the 10/532953 application filed on April, 27, 2005.
2. Claims 1-20 are pending and have been fully considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1-3, 9-14, 16-17, & 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by TIFFANY in US 5508200.

With respect to Claim 1, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent (Abstract) of which the reaction conditions during sample analysis are similar (common test area on the media at discreet locations, resulting in optical changes at the location(Abstract).

With respect to Claim 2, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples for isolating variations in the intensity changes over a period of time. The relative intensity is then determined as the ratio of the sample intensity to the blank and in which the measurement on the sample may be made with different cameras at independent stations (column 12, lines 9-25).

TIFFANY et al. also teach of monitoring individual chemical and immunochemical tests

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at the discrete locations about the common test area (measurement conditions different from each other)(column 3, lines 45-67 & column 4, lines 1-4).

With respect to Claim 3, TIFFANY et al. teach of the corrections being performed based on the results of two or more blank measurements (multiple samples=multiple blank measurements for correction) (column 12, lines 10-38))(column 3, lines 45-67 & column 4, lines 1-4).

With respect to Claim 9, TIFFANY et al. teach of the sample being blood (column 13, lines 25-34).

With respect to Claim 10, TIFFANY et al. teach of the analysis items including bilirubin, inorganic phosphorus, glucose, uric acid, creatinine, etc.(column 13, lines 25-34).

With respect to Claim 11, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent(Abstract) of which the reaction conditions during sample analysis are similar(common test area on the media at discreet locations, resulting in optical changes at the location(Abstract). Also, TIFFANY et al. teach of calculating the negative logarithm of each area which represents the change in optical density (column 13, lines 15-19).

With respect to Claim 12, TIFFANY et al. teach of computation means to perform correction based on the results of two or more blank measurements multiple samples=multiple blank measurements for correction) (column 12, lines 10-38))(column 3, lines 45-67 & column 4, lines 1-4).

With respect to Claim 13, TIFFANY et al. teach of correction means for obtaining corrections of data based on blank measurements column 12, lines 10-38))(column 3, lines 45-67 & column 4, lines 1-4).

With respect to Claim 14, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent(Abstract) of which the reaction conditions during sample analysis are similar(common test area on the media at discrete locations, resulting in optical changes at the location(Abstract).

With respect to Claim 16, TIFFANY et al. teach of channels for moving the sample wherein the reagents are in the channels (column 9, lines 1-10).

With respect to Claim 17, TIFFANY et al. teach of the sample moving by capillary action in the channels (column 7, lines 43-53).

With respect to Claim 19, TIFFANY et al. teach of directly applying samples to the same reaction site (column 14, lines 23-26).

With respect to Claim 20, TIFFANY et al. teach of the analysis part having a construction in which the reagent is on a supporting carrier(base) in which the carrier may be either an absorbent matrix or a microcuvette plate(column 3, lines 50-56).

4. ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over TIFFANY in US 5508200.

With respect to Claim 18, TIFFANY et al. teach of channels for moving the sample wherein the reagents are in the channels (column 9, lines 1-10). It would be obvious to one of ordinary skill to connect all the samples to one channel inlet in order to allow part of the sample to flow through each channel without tampering with the sample.

8. Claims 4-8, & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over TIFFANY in US 5508200 in view of BOLLIN in 4485176.

With respect to Claim 4, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent (Abstract) of which the reaction conditions during sample analysis are similar (common test area on the media at discrete locations, resulting in optical changes at the location (Abstract)). TIFFANY et al. do not teach of a reaction condition being the pH of the reaction liquid.

BOLLIN et al. teaches of a reaction condition being the presence of an alkaline environment (reaction condition = pH) (Abstract). It would have been obvious to combine the blank correction for analyzing samples of TIFFANY with the alkaline reaction environment of BOLLIN due to the fact that it is commonly known to use alkaline or acidic environments to aid in the determination of concentration of species (protein) in samples (column 1, lines 20-27).

With respect to Claim 5, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent (Abstract) of which the reaction conditions during sample analysis are similar (common test area on the media at discrete locations, resulting in optical changes at the location (Abstract)). TIFFANY et al. do not teach of a reaction condition being whether or not a surfactant is included in the liquid.

BOLLIN et al. teach of a reaction condition being a surfactant being included in the reaction liquid (Abstract). It would have been obvious to combine the blank

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correction of TIFFANY with the use of a surfactant to BOLLIN since it is commonly known in the art to use a surfactant to increase the solubility of organic compound in solution.

With respect to Claim 6, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent(Abstract) of which the reaction conditions during sample analysis are similar(common test area on the media at discrete locations, resulting in optical changes at the location(Abstract)). TIFFANY et al. do not teach of a performing the blank measurement in an acidic, alkaline, or surfactant blank system.

BOLLIN et al, however teach of performing a blank measurement in an alkaline measurement system (column 2, lines 34-46). It would have been obvious to combine the blank correction for analyzing samples of TIFFANY with the alkaline reaction environment of BOLLIN due to the fact that it is commonly known to use alkaline or acidic environments to aid in the determination of concentration of species(protein) in samples(column 1, lines 20-27).

With respect to Claim 7, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent(Abstract) of which the reaction conditions during sample analysis are similar(common test area on the media at discrete locations, resulting in optical changes at the location(Abstract)). TIFFANY et al. do not teach of a reaction condition being whether or not a surfactant is included in the liquid.

BOLLIN et al. teach of a reaction condition being a surfactant being included in the reaction liquid (Abstract) in an alkaline or acidic environment (column 1, lines 20-

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27). It would have been obvious to combine the blank correction of TIFFANY with the use of a surfactant to BOLLIN since it is commonly known surfactants are used to help solubilize organic compounds(i.e. adjust the pH to neutral).

With respect to Claim 8, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent(Abstract) of which the reaction conditions during sample analysis are similar(common test area on the media at discrete locations, resulting in optical changes at the location(Abstract). TIFFANY et al. do not teach of performing an analysis with the surfactant measurement condition and the acidic or alkaline measurement system.

BOLLIN et al. teach of a reaction condition being a surfactant being included in the reaction liquid (Abstract) in an alkaline or acidic environment (column 1, lines 20-27). It would have been obvious to combine the blank correction of TIFFANY with the use of a surfactant to BOLLIN since it is commonly known surfactants are used to help solubilize organic compounds (i.e. adjust the pH to neutral) and the fact that it is commonly known to use alkaline or acidic environments to aid in the determination of concentration of species (protein) in samples (column 1, lines 20-27).

With respect to Claim 15, TIFFANY et al. teach of performing blank correction (column 12, lines 10-38) when analyzing a plurality of samples comprising sample and reagent(Abstract) of which the reaction conditions during sample analysis are similar(common test area on the media at discrete locations, resulting in optical changes at the location(Abstract). TIFFANY et al. do not teach of a performing the blank measurement in an acidic, alkaline, or surfactant blank system.

BOLLIN et al, however teach of performing a blank measurement in an alkaline measurement system (column 2, lines 34-46). It would have been obvious to combine the blank correction for analyzing samples of TIFFANY with the alkaline reaction environment of BOLLIN due to the fact that it is commonly known to use alkaline or acidic environments to aid in the determination of concentration of species(protein) in samples(column 1, lines 20-27).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Warden, Jill can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.F. /Jill Warden/
Supervisory Patent Examiner, Art Unit 1797